

<b>Office Action Summary</b>	<b>Application No.</b> 09/807,066	<b>Applicant(s)</b> COGHLAN ET AL.	
	<b>Examiner</b> Golam M M Shameem	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,5-17 and 19-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,4 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,2,5-17 and 19-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Election/Restriction***

Applicant's election with traverse of Group III (claims 3-4 and 18) drawn to a compound of formula (IC), in paper No.7 filed October 15, 2002, is acknowledged. The traversal is on the ground(s) that the elected invention Group could be extended to other Groups because "the claimed invention arose from a singular research effort, the compounds, methods of treatment, and process claims should be considered as of a single application" (Remarks, page 3). This is not found persuasive because the products of groups I to XI differ materially in structure and in element (lack unity of invention) from each other and, are capable of supporting their own patents. Therefore, to not restrict would impose a burden in the examination of this application.

Restriction was based on PCT Rule 13.1, 13.2 and Annex B part 1(b) together with 37 CFR 1.475 and 1.499 for lacking unity of invention because of lacking a significant structural element qualifying as the special technical features.

PCT Rule 13.2 states that the international application shall related to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Should applicant traverse on the ground that the groups I-XI are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing groups I-XI to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art (In the instant case, then there could have been no patentability of all the claims over Seres et al) the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention.

For these reasons, applicant's arguments are found unpersuasive and, since 35 U.S.C. 101 allows one patent per invention, the requirement for restriction in Paper No. 6 is still deemed proper and is therefore made FINAL.

Applicants preserve their right to file a divisional on the non-elected subject matter.

### *Status of Claims*

Claims 1-23 are pending in this application. Claims 1-2, 5-17 and 19-23 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Seres et al (US Pat No. 4,353,734). Applicant claims a pyrrole-2, 5-diones compounds which may be useful as GSK-3 inhibitors. Seres et al disclose a series of maleimide and succinimide compounds one of which anticipates the instantly claimed compound (see, column 5, Example 5, lines 7-20).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seres et al (US Pat No. 4,353,734). Applicant claims a pyrrole-2, 5-diones compounds which may be useful as GSK-3 inhibitors.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Seres et al teach the generic compounds of maleimide and succinimide and their herbicidal method of use thereof (see whole patent especially columns 2, 3, 5 and 6).

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

Seres '734 disclosed structurally similar compounds of the claims wherein a pyrroline compound is disubstituted with the same phenyl group in 3 and 4 position of the core structure. The difference between the instant claims and Seres compounds is that instead of hydrogen, alkyl, aryl or aralkyl (claim 3) in R substitution, Seres '734 has N-protected group with ester substitution (see column 1-5, including Example 5) and R4 is also could be hydrogen (column 2, lines 45-55).

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

One having ordinary skill in the art would be in possession of the claimed compound generically **because** Seres et al taught that the final products are made from formula IV (column

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3, lines 1-14) wherein guided by anticipating example pointed out supra (section 102). One in possession of the above reference would be motivated to make all the compounds of Seres et al with the expectation that they would have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979). Applicants should note that a generic teaching is grounds for obvious type of rejection.

***Claim Rejections - 35 USC § 112-second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 USC § 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 18, the phrase “and/or” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It is also not clear from the specification what is applicant’s intent by this expression. It is suggested to amend the above phrase with in the context and scope of the claim in order to overcome the rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18, is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation "A method for the treatment and/or prophylaxis" lacks written description in the specification. The specification does not provide essential description to carry out the invention and is therefore not enabled. The invention claimed is not described and/or is not enabled in such a way as to satisfy the statutory requirements within the purview of 35 U.S.C. 112 first paragraph.

### *Claim Objections*

Claim 4, is objected to as being dependent upon a rejected base claim 3 and claim 3 is also objected to as being improperly dependent on a non-elected claim 2. The elected subject matter of the claims should be rewritten in independent form including all of the limitations of the base claim and any intervening claims. Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (703) 305-0116. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.


When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

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